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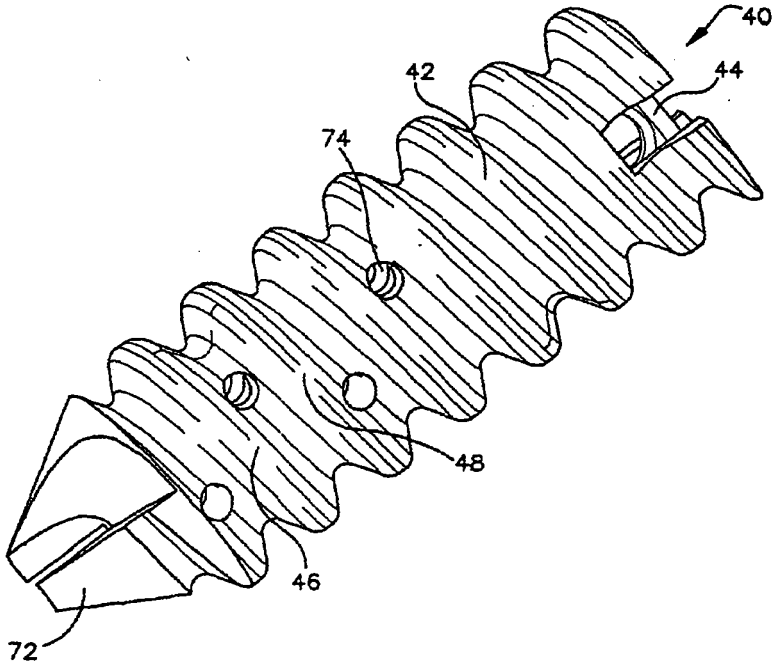
(54) Title: BONE ANCHORING SYSTEM



(57) Abstract: A bone anchoring system (40) comprises a bone screw (42) and a mechanical insert (44) received in a central bore (50) of the bone screw (42). The bone screw (42) defines a self-tapping, self-boring tip (72) for easy bone insertion as well as through-holes or other openings (74) for receipt of new bone growth. The insert (44) can be replaceably mounted in the bone screw (42), and a variety of different attachment structures (58) can be defined in the proximal end of the insert (44) for securing to suture thread, tissue or other prosthetic device.

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BONE ANCHORING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

This application is based on provisional application serial number 60/147,262, filed August 4, 1999, the disclosure of which is incorporated herein by reference and the benefit of which is hereby claimed.

BACKGROUND OF THE INVENTION

Field

The present invention relates to an improved bone anchoring system for attaching living tissue or a prosthetic device to bone.

Background

U.S. Patent No. 5,584,695, the disclosure of which is also incorporated herein by reference, describes in Figures 7 and 8 a two-part bone anchoring system composed of an anchoring screw and a coupling pin. The

anchoring screw is intended to be screwed into a hole previously drilled into the bone. The coupling pin includes a shank shaped to be received in a bore hole in the anchoring screw and, on its proximal end, an eyelet for receiving and holding a suture or prosthetic device. The shank of the coupling pin is made from a material which expands in response to body heat, thereby locking the coupling pin in place in the bore hole of the anchoring screw.

Self-tapping cannulated bone screws are also known. See, for example, U.S. Patent No. 5,516,616 and U.S. Patent No. 5,571,139, the disclosures of which are also incorporated herein by reference.

Although the anchoring systems of these patents provide some advantages over earlier technology, there is still a need to provide more secure anchoring, greater flexibility and simpler operation than possible in these systems.

SUMMARY OF THE INVENTION

This and other objects are accomplished by the present invention in accordance with which a new bone anchoring system is provided. This system is composed of a novel self-boring, self-tapping bone screw configured to enhance bone growth and a mechanical

insert for mounting in the bone screw. The insert can carry different attaching structures for attachment to suture thread, tissue or other prosthetic device and can be mounted in the bone screw in a variety of different ways. By this means, the inventive anchoring system can be arranged in a variety of different configurations simply and easily and yet still provide secure mounting in all configurations.

Thus, the present invention provides a new bone anchoring system comprising a bone screw defining a self-tapping, self-boring tip and a central bore, and a mechanical insert having a distal end for being received in the central bore and mechanically held by the bone screw, the insert further having a proximal end defining an attachment structure for securing to suture thread, tissue or other prosthetic device, wherein the bone screw includes at least one opening for receipt of new bone growth when the bone screw is screwed in place in a bone.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be more readily understood by reference to the following drawings wherein:

Figure 1 is an isometric view showing one embodiment of the inventive bone anchoring system in an assembled condition;

Figures 2, 10 and 11 are partial sectional view of the inventive bone anchoring system of Figure 1;

Figures 3 and 9 are additional views of the inventive bone anchoring system of Figure 1;

Figure 4 is a sectional view similar to Figure 2 showing another embodiment of the invention in which the distal end of the bone screw of the inventive bone anchoring system is essentially solid;

Figures 5 and 7 illustrate additional embodiments of the present invention in which the bone screw and insert of the inventive bone anchoring system are made from a single, integral piece of material;

Figure 6 is a sectional view of the bone anchoring system of Figure 5;

Figures 8, 20, 21, 22, 23 and 24 illustrate a drive mechanism useful for inserting the bone screw of the inventive anchoring system in place in a bone;

Figures 12, 13, 14, 15 and 16 illustrate different mechanical inserts that can be used in the inventive bone anchoring system;

Figures 17, 18 and 19 are sectional views illustrating still another embodiment of the inventive bone anchoring system similar to the system of Figure 4; and

Figure 25 illustrates the self-boring, self-tapping tip carried on the distal end of the bone screw anchoring systems of Figures 1, 2, 3, 9, 10 and 11.

DETAILED DESCRIPTION

The invention comprises a bone anchoring system for attaching sutures, soft tissue, dental prostheses, etc. to a bone and a device to drive the bone anchor into place. The system has the following features:

(1) self, tapping/driving attributes to eliminate the need for predrilling and/or tapping. These anchors may have one or more cutting surfaces;

(2) a hole, slot, hook or similar attribute at the end of the anchor to allow attachment of sutures, tissue, prostheses, etc.;

(a) a version with integral heads to allow the anchor to be used in specific surgical applications such as orthopedic, plastic and reconstructive, dental, etc.;

(b) a version with interchangeable heads to allow the anchor to be used in multiple applications by

replacing the head, such as orthopedic, plastic and reconstructive, dental, etc.;

(3) a geometry which will allow the anchor to be placed with the end of the bone anchor below the surface of the bone;

(4) surface and other physical modifications of the anchor to promote bone ingrowth which assists in preventing the anchor from backing out;

(5) optional center hole to core the bone in an effort to improve bone ingrowth and increase the ease of implantation;

(6) device to drive the anchor into the bone and a ratchet or similar mechanism on the driver to increase ease of use for the surgeon.

The self-driving and tapping bone anchor eliminates the need to bone drill hole or tapping. A recessed slot or thread holes allows the bone anchor to be utilized with any suture or tissue securing material, or as an attachment site for a prosthetic device, such as dental implant. Surface modifications such as texturing and perforations allow osseous ingrowth for bone ingrowth.

Bone anchors may be utilized in any surgical procedure that requires soft tissue attachment to bone.

Bone anchors are currently used in orthopedic surgery, hand surgery, plastic and reconstructive surgery, otolaryngology head and neck surgery, ophthalmologic surgery and dental procedures. Tendons, ligaments, muscles and skin are common soft tissues which may be anchored to bone. Bone anchors may also be utilized to support and/or attach dental prostheses.

As shown in Figures 1, 2, 3, 9, 10 and 11, the inventive bone anchoring system 40 in one embodiment is composed of bone screw 42 and a separate mechanical insert 44, both of which are made from biocompatible materials such as titanium or the like. Bone screw 42 includes a shank 46 defining screw threads 48 for allowing bone screw 42 to be securely mounted in a bone. In addition, bone screw 42 further defines central bore 50, which passes through the distal end of shank 46 so that distal end or tip 72 of the bone screw is annular in configuration. Tip 72 is shaped as illustrated in Figure 25 to be both self-boring and self-tapping. Accordingly, bone screw 42 can be inserted in place without pre-drilling a pilot hole, although a pilot hole can be provided if desired.

As shown in Figures 2, 10 and 11, central bore 50 also extends to the proximal end of the bone screw

where it receives mechanical insert 44. The structure of this particular mechanical insert is more clearly shown in Figure 12. Central bore 50 of bone screw 42 is provided with screw threads 52 for mating with corresponding screw threads 56 carried on the distal end 54 of mechanical insert 44. The proximal end of mechanical insert 44 is provided with an attachment structure 58 for securing suture thread, tissue or other prosthetic device to the inventive bone anchoring system. In the particular embodiment shown, the attachment structure is a closed eyelet 60. By "closed" is meant that the eyelet opening 62 in the eyelet is fully defined throughout a full 360 degrees so that a suture thread fed through this eyelet opening cannot slip out except through its ends. In contrast, an "open" eyelet is one such as illustrated in Figures 13 and 14 where a notch or opening is provided in some portion of the eyelet's arc such that eyelet function like a hook.

In any event, Figures 13 and 14 illustrate that mechanical insert 44 of Figures 1, 2 and 9 10, 11 and 12 can be replaced by mechanical inserts 64 and 66 of Figures 13 and 14, respectively, to provide similar yet different attachment functions. Still another type of

attachment function can be provided by the socket type attachment structure 68 as shown in mechanical insert 70 of Figures 15 and 16. These figures illustrate that a variety of different attachment functions can be readily and easily provided by the inventive bone anchoring system simply by replacing mechanical insert 44 with another mechanical insert having the desired attachment structure.

As illustrated in Figures 1, 2 and 11, shank 46 of bone screw 42 defines multiple through-holes 74, at least some of which preferably communicate with central bore 50. In the particular embodiment shown, these through-holes are arranged at essentially right angles with respect to the central axis of the bone screw. Alternatively, one or more through-holes 74 can be arranged at any other desired angle, although it is preferable that they be arranged in a generally transverse direction. By a "generally transverse" direction is meant that the through-holes are arranged at an angle of at least 45 degrees with respect to the center axis of the bone screw. Through-holes which do not pass through the center axis of the bone screw are "generally transverse" when they are arranged at an angle of at least 45 degrees with a line parallel to

this central axis. Through-holes which are not straight are "generally transverse" if they are "generally transverse" within the above meanings at their centers.

Through-holes 74 are provided to enhance the osteogenesis process - i.e., to foster bone growth into the interior of the bone screw. To this end, these through-holes (as well as central bore 50) can be coated or provided with a material fostering osteo-inductive or osteo-conductive bone growth, if desired. Examples are bone growth hormones, tricalcium phosphate and the like. Bone growth will occur into the interior of the bone screw, in accordance with the present invention, by growing into through-holes 74. Where through-holes 74 communicate with central bore 50, bone may grow into central bore 50 through these through-holes. Where through-holes 74 do not communicate with central bore 50, bone will nonetheless grow into the interior of bone screw 42 by growing into these through-holes. Also, even where no through-holes 74 are provided, bone will nonetheless grow into the interior of bone screw 42. This is because, as shown in Figure 25, annular tip 72 is not blocked by any other part of the inventive bone anchoring system (or

attached suture thread or prosthetic device) and hence is open to receive new bone growth.

In accordance with the present invention, therefore, bone screw 42 includes at least one opening for receipt of new bone growth when the bone screw is screwed in place in a bone. This enhances the osteogenesis process, thereby locking the bone screw in place over time to provide an exceptionally secure connection. At the same time, however, the inventive bone anchoring system can be put to a variety of different uses simply by choosing a mechanical insert 44 having a different attachment function. And, because mechanical insert 44 is removable, this attaching function can be changed over time as desired. Thus, the inventive anchoring system combines highly flexibility in terms of different possible uses with superior performance in terms of anchoring strength.

A second embodiment of the inventive bone anchoring system is illustrated in Figure 4. In this embodiment, central bore 150 in bone screw 142 terminates in the proximal end 146 of the bone screw. Accordingly, the distal end 152 of the bone screw, except for through-holes 174, is essentially solid.

Figures 17, 18 and 19 illustrate a third embodiment of the inventive bone anchoring system. This embodiment is essentially the same as the embodiment of Figure 4, except that distal end 254 of mechanical insert 244 is snap-fit into the proximal end 246 of bone screw 242. In the particular embodiment shown, ridges 255 carried on the distal end of the mechanical insert are received in annular detent 268 defined in the proximal end 270 of bone screw 242. This structure allows mechanical insert 244 to rotate freely about the central axis of the bone screw, as may be desired in some applications.

Figures 5, 6 and 7 illustrate still additional embodiments of the inventive bone anchoring system in which the bone screw and mechanical insert are formed from a unitary, single piece of material. In these embodiments, a central bore has been eliminated whereby the inventive bone anchoring system is essentially solid. However, as in the embodiments of Figures 4, 17, 18 and 19, the distal end of the bone screw in these embodiments is also provided with through-holes 322 for fostering bone growth into the interior of the bone screw. In the embodiment of Figures 5 and 6, the proximal end of the bone screw is provided with a drive

structure comprising detents 340 for mating engagement with corresponding prongs carried on the head of a driver used for driving the bone screw in place. As shown in Figure 6, a hole 346 is also provided in the distal end of the bone screw between these detents for receipt of a suture thread, tissue or other prosthetic device. In the embodiment of Figure 7, the proximal end of the bone screw defines an eyelet 350 having essentially the same structure as closed eyelet 60 of mechanical insert 44 of Figures 1, 2 and 9-12.

Figures 8, 20, 21, 22, 23 and 24 illustrate a driver that can be used to drive the bone screw of the inventive bone anchoring system in place. This driver includes a handle 420, a drive shaft 428 mounted on the handle and a chuck 430 mounted on the drive shaft. Chuck 430 is adapted to receive and hold a variety of different, interchangeable drive heads so that bone screws of different sizes and having different drive structures can be accommodated by the same drive tool.

The particular drive head 444 illustrated in these figures is composed of a support shaft 446 having essentially the same diameter as the bone screw to be driven in place and support sleeve 448. The outer cylindrical surface of support shaft 446 defines a

series of axially-spaced annular detents 450, while the drive structure on the distal end of support shaft 446 includes projections 452 for mating engagement with corresponding detents on the proximal end of bone screw 442 to be driven.

The proximal end of support sleeve 448 carries an annular projection 460 for receipt in annular detents 450 of support shaft 446. In addition, support sleeve 448 is flexible enough so that it can move axially in response to moderate force applied by hand, with annular projection 460 being received by different annular detents 450 in response to this movement.

As illustrated in Figure 23, this structure allows support shaft 446 to carry and guide bone screw 442 to a desired position before being inserted into a bone. As shown in Figure 24, this structure also allows automatic withdrawal of bone screw 442 from drive head 444 as the bone screw is screwed into place. This automatic withdrawal occurs as a result of bone at the lip of the bone opening created when the bone screw is driven in place abutting the distal end 468 of support sleeve 448, thereby driving this support sleeve rearwardly as bone screw 442 is driven in place.

Although only a few embodiments of the present invention have been described above, it should be appreciated that many modifications can be mad without departing from the spirit and scope of the invention. All such modifications are intended to be included within the scope of the present invention, which is to be limited only by the following claims.

We claim:

1. A bone anchoring system comprising:

(a) a bone screw defining a self-tapping, self-boring tip and a central bore, and

(b) a mechanical insert having a distal end for being received in the central bore and mechanically held by the bone screw, the insert further having a proximal end defining an attachment structure for securing to suture thread, tissue or other prosthetic device, wherein the bone screw includes at least one opening for receipt of new bone growth when the bone screw is screwed in place in a bone.

2. The system of claim 1, wherein the mechanical insert and bone screw are separately formed.

3. The system of claim 2, wherein the bone screw includes a shank defining screw threads, the shank further defining at lest one through-hole for receipt of new bone growth.

4. The system of claim 3, wherein the shank defines multiple through-holes for receipt of new bone growth.

5. The system of claim 3, wherein the through-holes are generally transverse to the axis of the bone screw.

6. The system of claim 5, wherein the central bore terminates in the proximal end of the bone screw whereby the distal end of the bone screw, except for the through-holes, is essentially solid.

7. The system of claim 3, wherein the central bore of the bone screw passes through the distal end of the shank whereby the distal end of the bone screw is annular in configuration, the self-tapping, self-boring tip of the bone screw being defined in this annular configuration.

8. The system of claim 7, wherein the shank of the bone screw defines multiple through-holes communicating with the bore hole.

9. The system of claim 8, wherein the through-holes are generally transverse to the axis of the bone screw.

10. The system of claim 2, wherein the bore hole of the bone screw passes through the distal end of the shank for receipt of new bone growth, the distal end of the bone screw being annular in configuration with the self-tapping, self-boring tip of the bone screw being defined in this annular configuration.

11. The system of claim 2, wherein the distal end of the insert threadedly engages the bone screw.

12. The system of claim 2, wherein the distal end of the insert is snap fit in the bone screw.

13. The system of claim 12, wherein the insert is rotatable with respect to the bone screw.

14. The system of claim 2, wherein the attachment structure comprises an eyelet or socket.

15. The system of claim 1, wherein the bone screw and mechanical insert are formed from a single, unitary piece of material.

16. A bone screw for use in a bone anchoring system, the bone screw including a shank defining screw threads and a central bore for receiving a mechanical insert on the proximal end of the bone screw, the central bore passing through the distal end of the shank whereby the tip of the bone screw is annular in configuration, a self-tapping, self-boring tip being defined in the annular tip of the bone screw, the shank further defining at least one through-hole for receipt of new bone growth.

17. The bone screw of claim 16, wherein the hole communicates with the central bore.

18. The bone screw of claim 17, wherein the shank defines multiple through-holes arranged generally transverse to the axis of the bone screw.

19. A bone screw for use in a bone anchoring system, the bone screw including a shank defining screw

threads, the distal end of the shank defining a self-tapping, self-boring tip, the shank further defining at least one through-hole for receipt of new bone growth, the bone screw defining a central bore for receiving a mechanical insert on the proximal end of the bone screw, the central bore terminating in the proximal end of the bone screw whereby the distal end of the bone screw, except for the through-holes, is essentially solid.

20. The bone screw of claim 19, wherein the shank defines multiple through-holes arranged generally transverse to the axis of the bone screw.

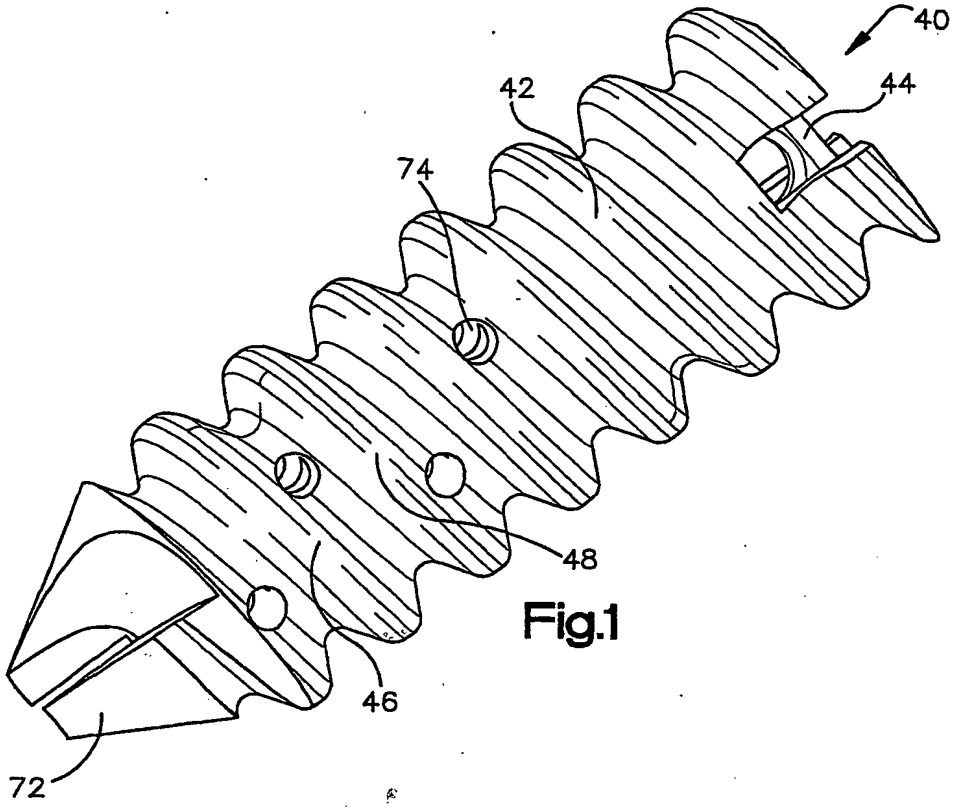

Fig.1

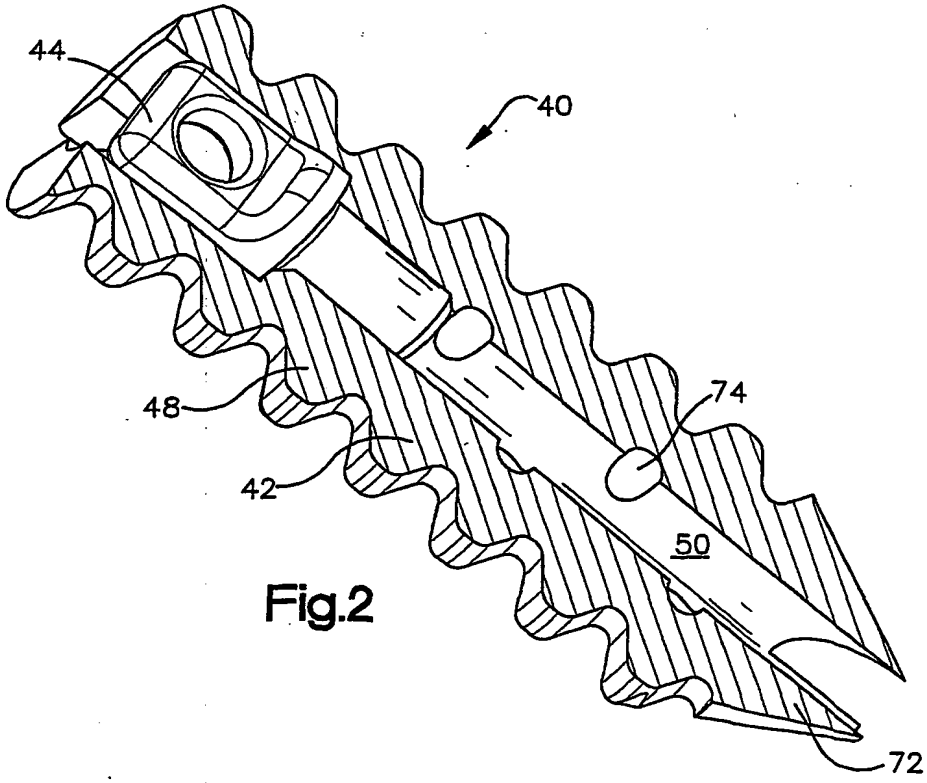

Fig.2

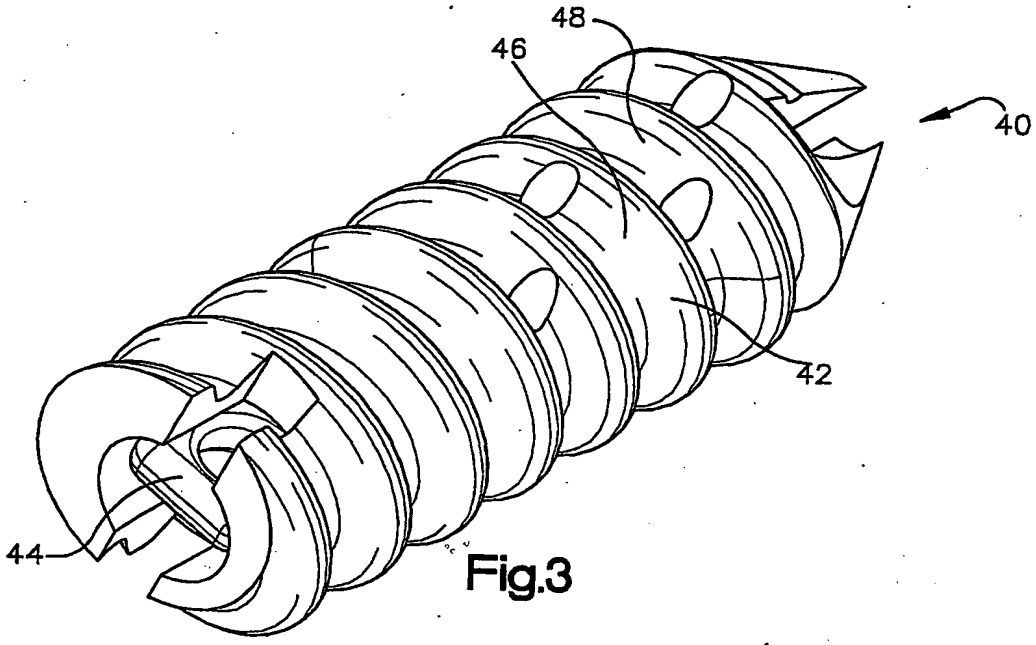

Fig.3

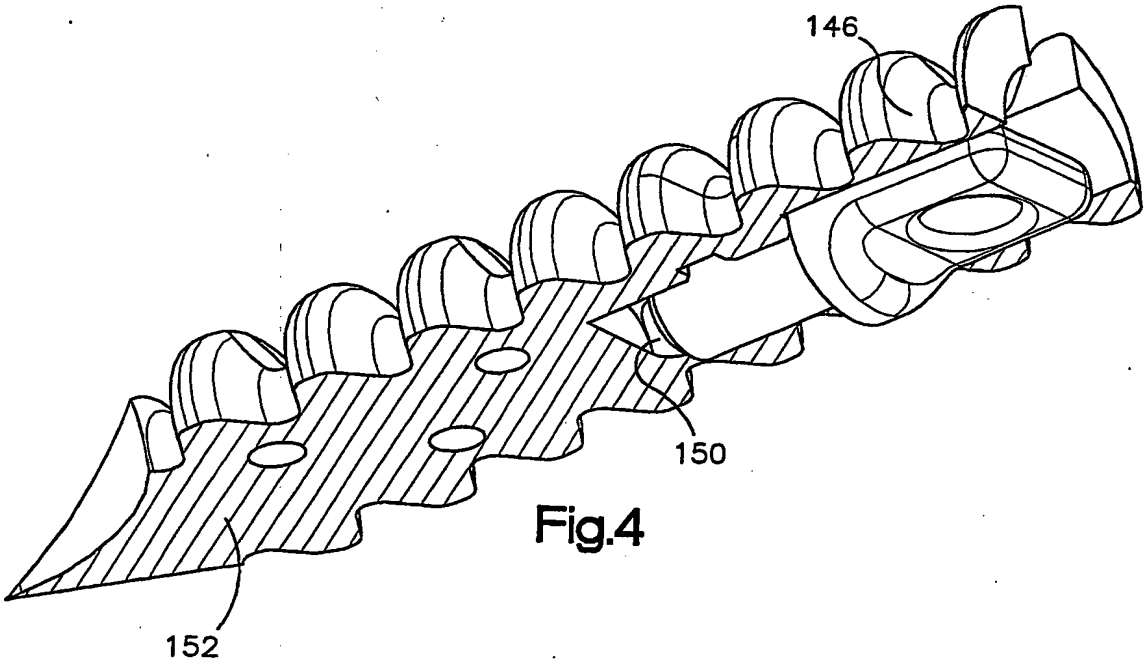

Fig.4

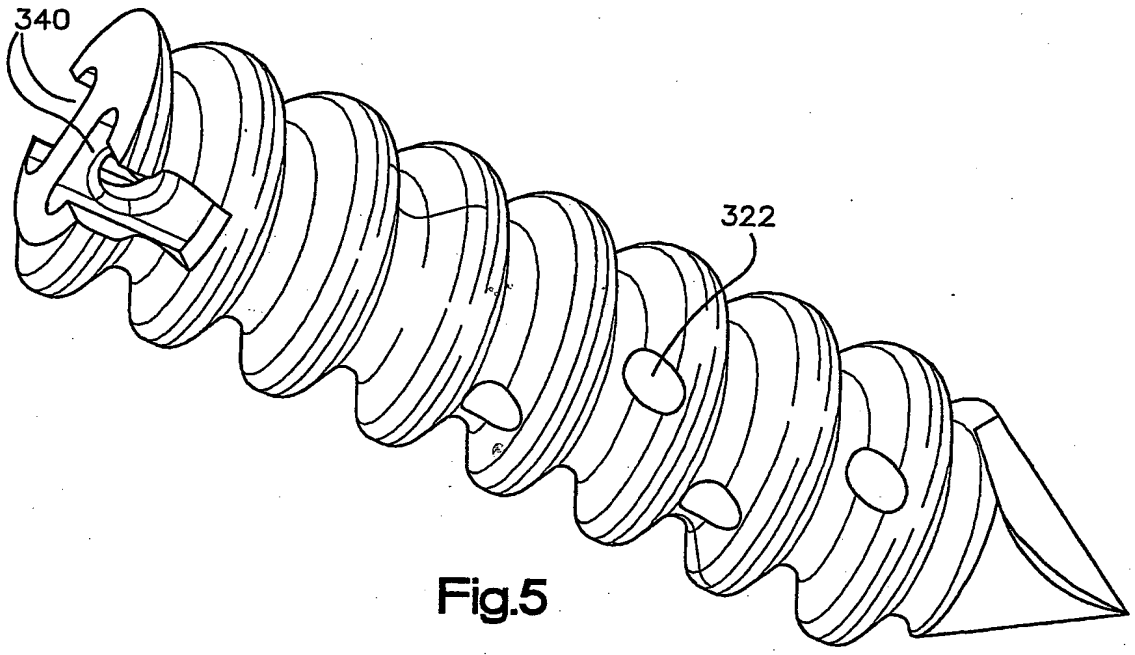

Fig.5

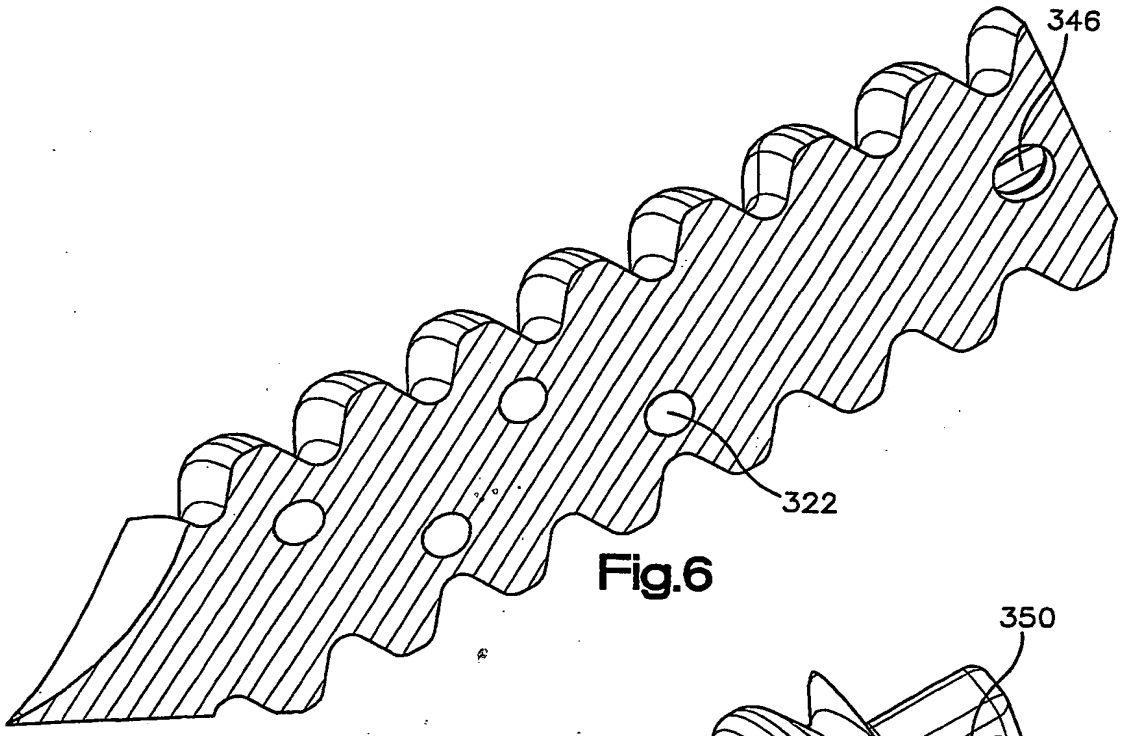

Fig.6

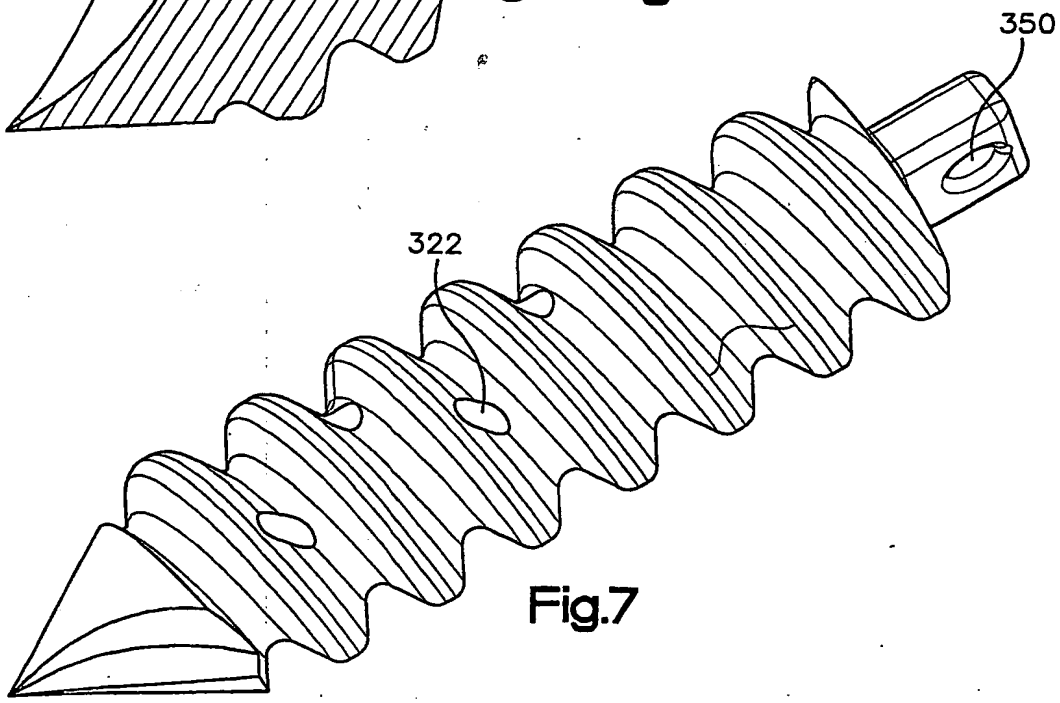

Fig.7

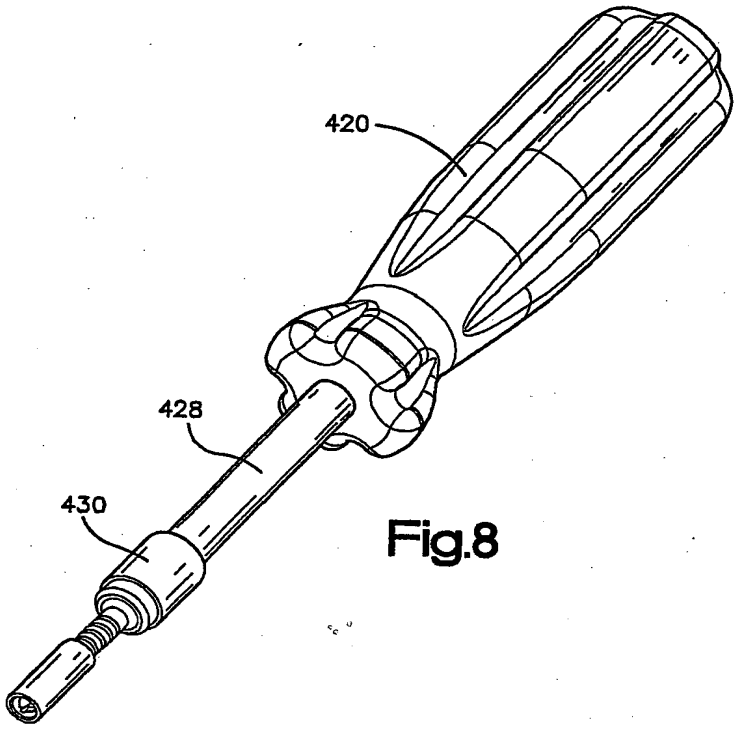

Fig.8

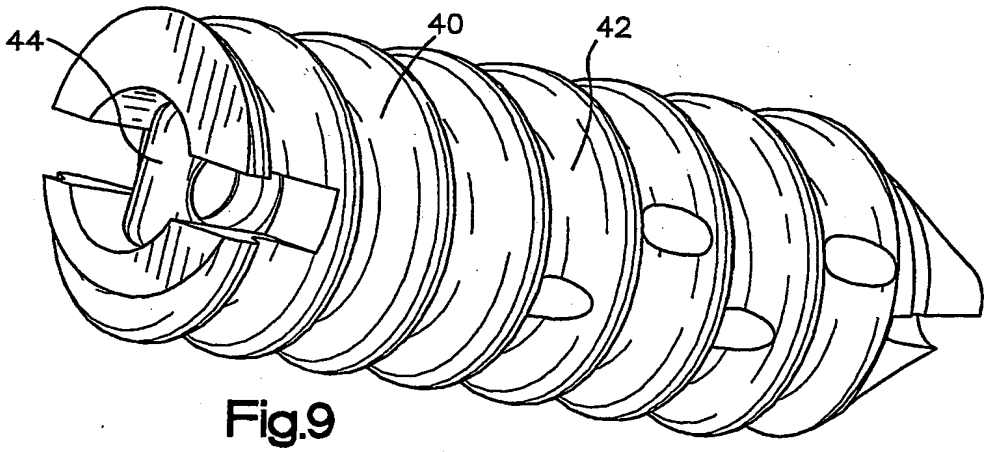

Fig.9

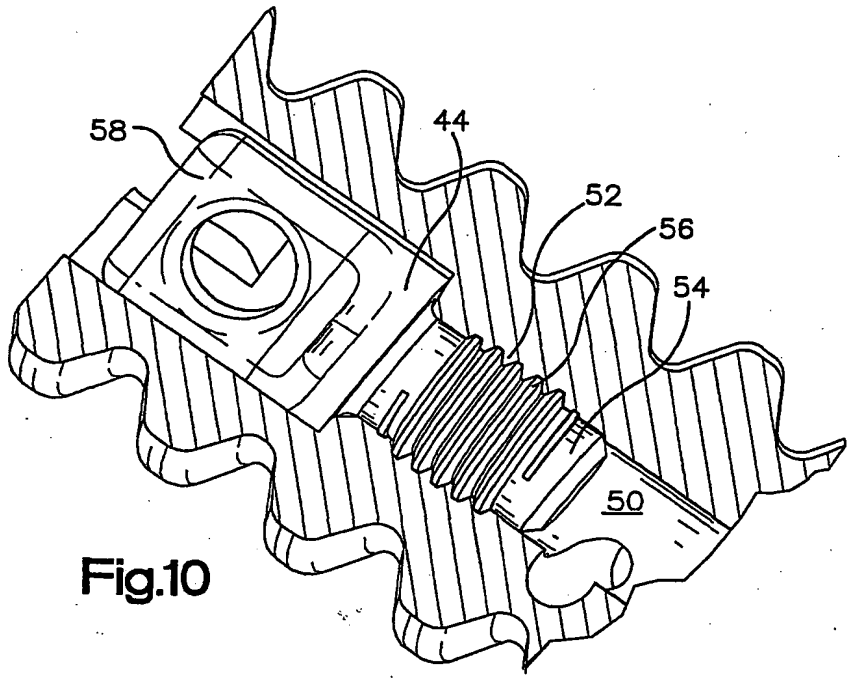

Fig.10

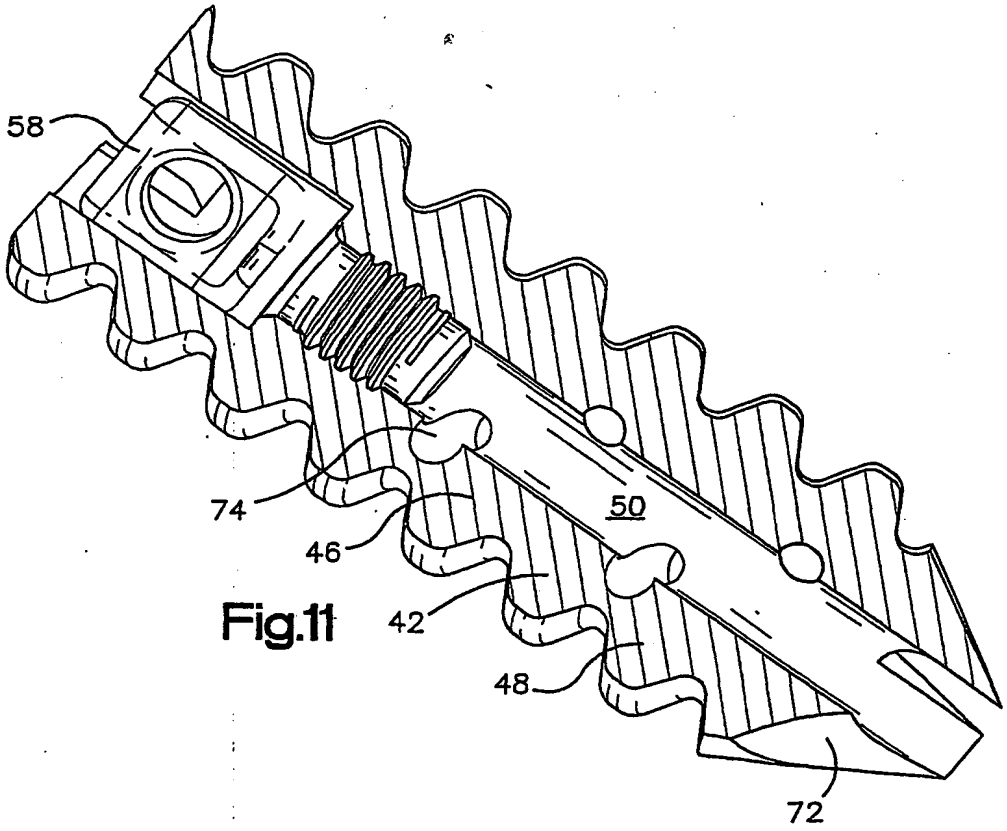

Fig.11

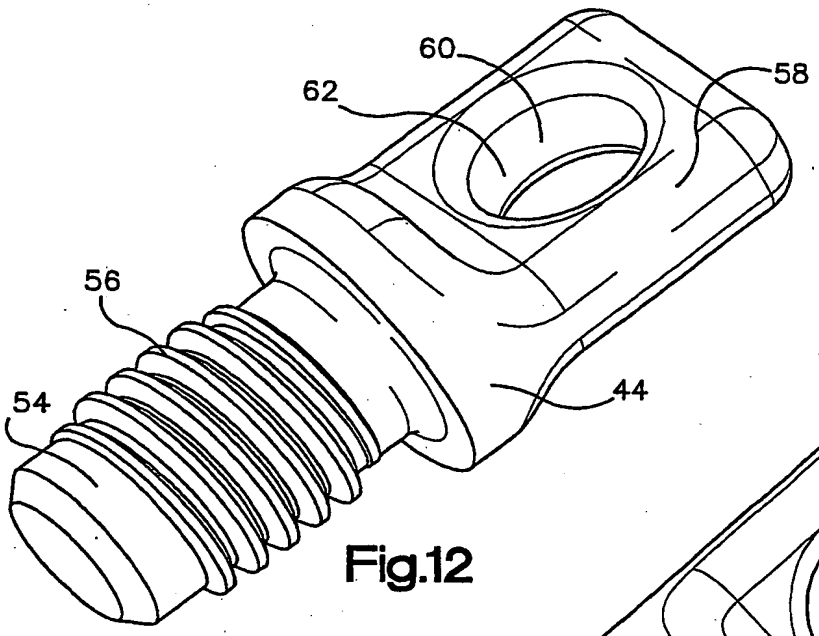

Fig.12

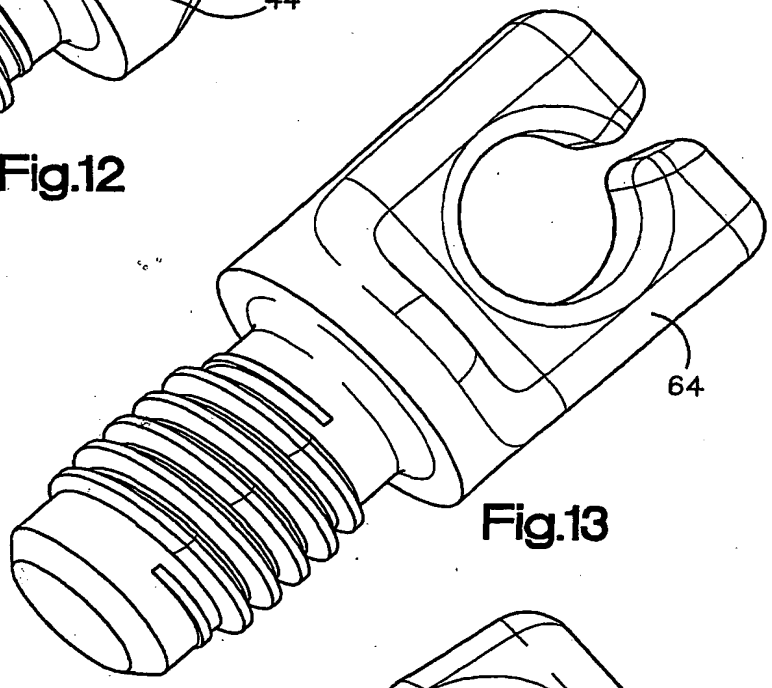

Fig.13

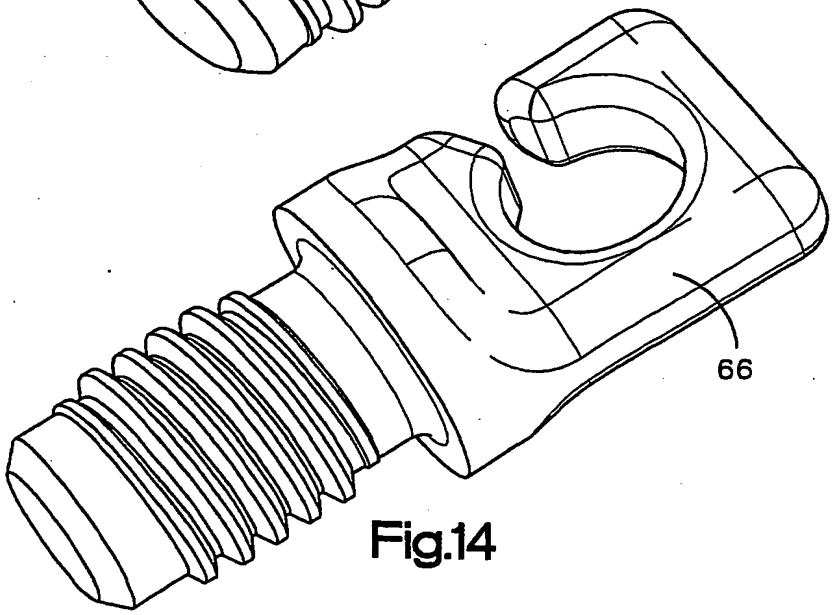

Fig.14

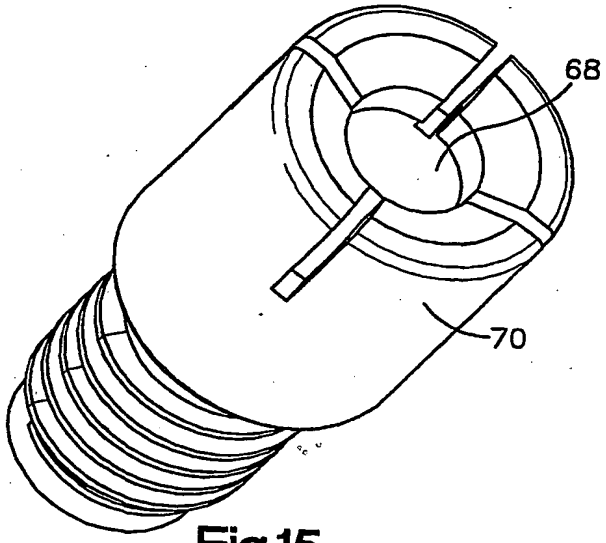

Fig.15

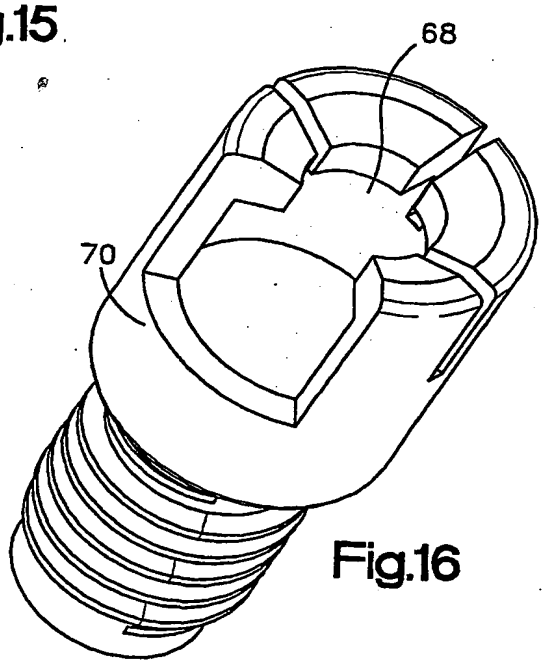

Fig.16

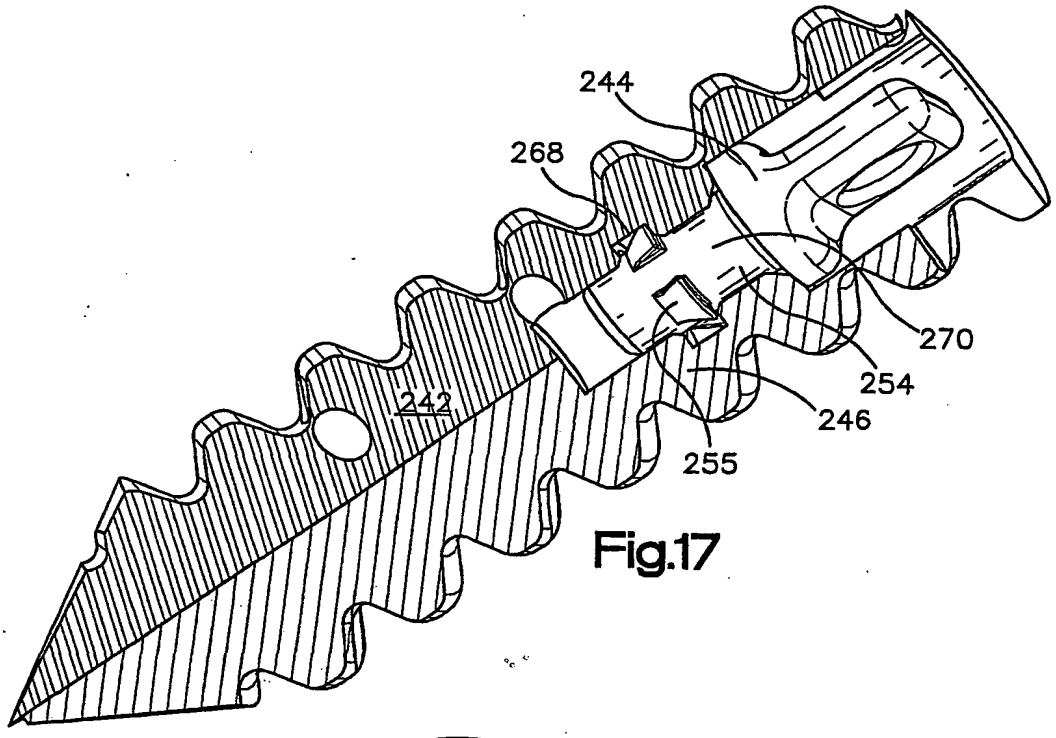

Fig.17

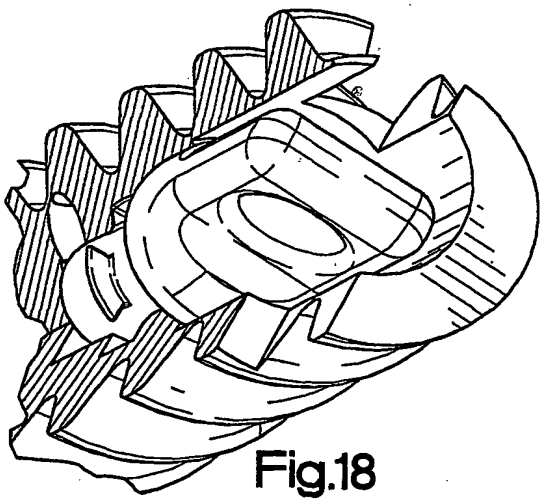

Fig.18

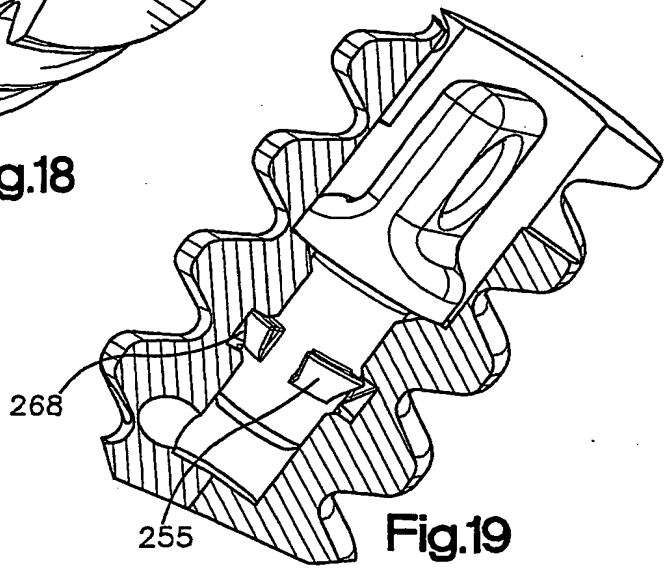

Fig.19

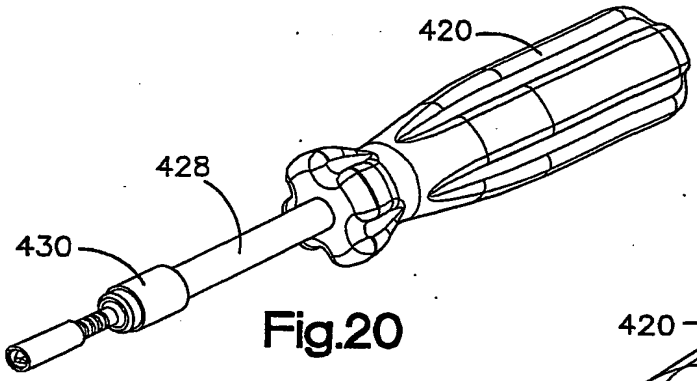

Fig.20

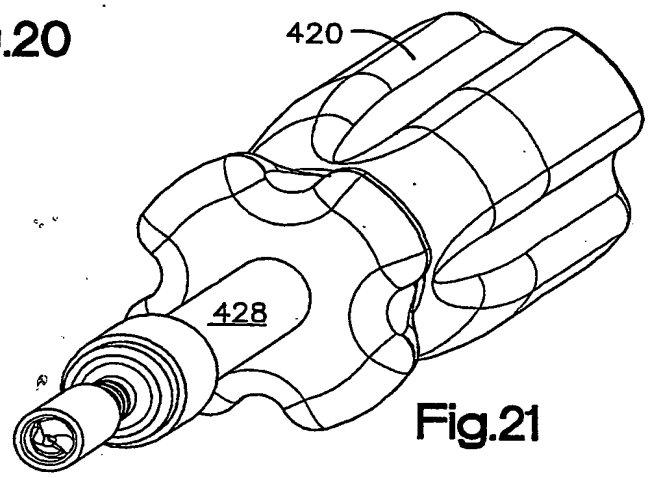

Fig.21

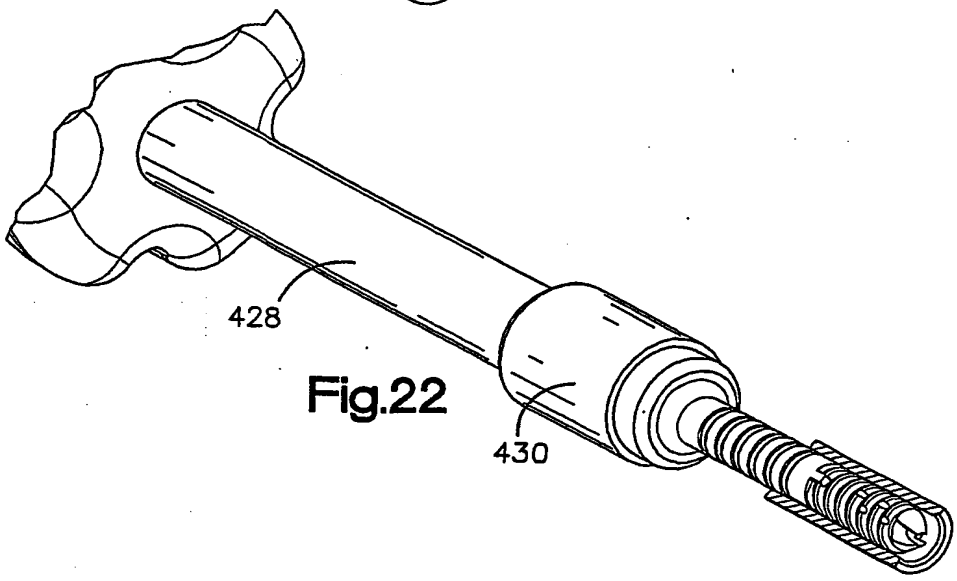

Fig.22

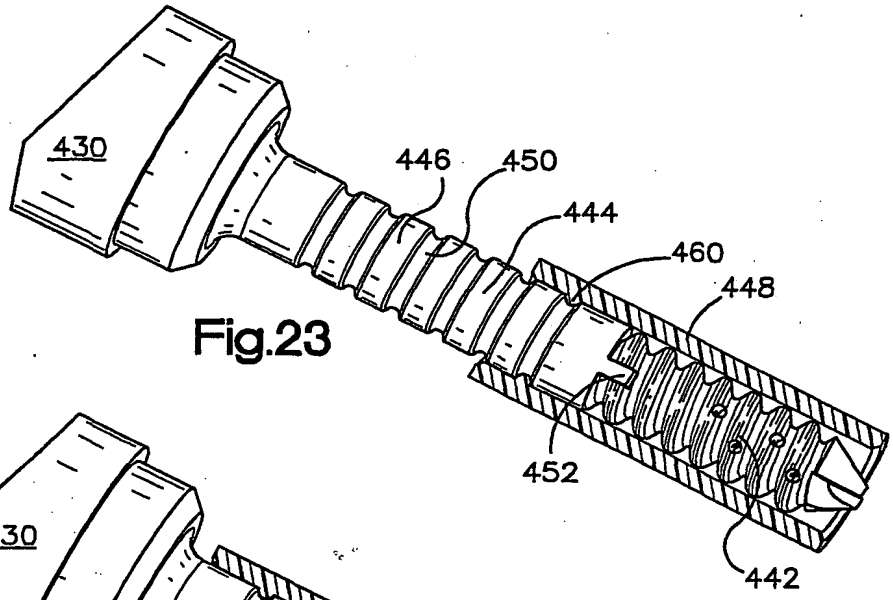

Fig.23

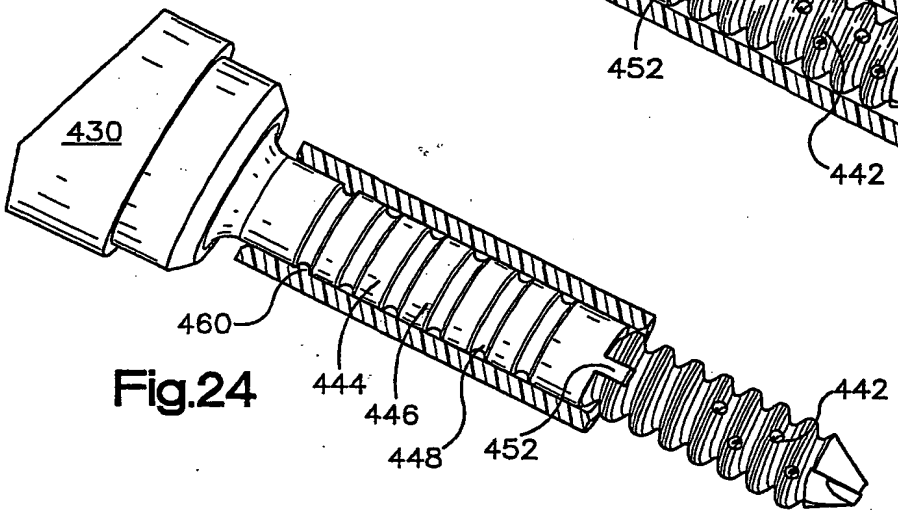

Fig.24

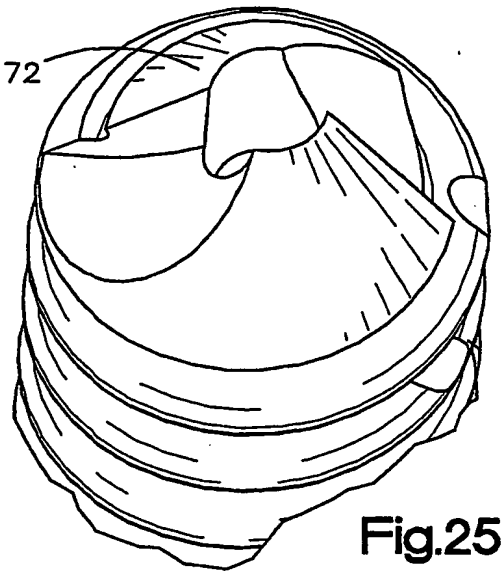

Fig.25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/24581

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/68
US CL : 606/72

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72,60,73,232,65,66

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,849,004 A (BRAMLET) 15 December 1998, see all document.	1-6,11, 14-2 0 --- 12,13
X	US 6,053,916 A (MOORE) 25 April 2000, see complete document.	16-18
X, P	US 6,210,376 B1 (GRAYSON) 03 April 2001, see complete document.	16-20
X	US 5,571,139 A (JENKINS, JR.) 05 November 1996, see complete document.	16,17
A	US 4,632,100 A (SOMERS et al) 30 December 1986, see complete document.	1-20

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Date of the actual completion of the international search 02 NOVEMBER 2001	Date of mailing of the international search report 25 JAN 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer EDUARDO C. ROBERT Diane Smith Telephone No. (703) 305-7333

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/24581

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,591,207 A (COLEMAN) 07 January 1997, see complete document.	1-20
A, P	US 6,214,012 B1 (KARPMAN et al) 10 April 2001, see complete document.	1-20

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer EDUARDO C. ROBERT Diane Smith Telephone No. (703) 305-7338

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/24581

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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